K072904

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

Many 8, 2008

MAY 21 2008

Submitter's Information:

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Trade Name, Common Name, Classification:

Trade Name:	Sonoca™ 180/195 Wound Care System
Common name:	Ultrasound wound cleaner
Classification name:	Low energy ultrasound wound cleaner, Instrument, ultrasonic Surgical

Predicate Device:

Device Classification Name	instrument, ultrasonic surgical	wound cleaner, ultrasound	instrument, ultrasonic surgical	pump, portable, aspiration (manual or powered)
510(k) Number	K012753	K062544	K050776	K992026
Device Name	SORING GMBH SONOCA 180/190	AR1000 ULTRASONIC WOUND THERAPY SYSTEM	AUSS-6 ULTRASONIC SURGICAL ASPIRATOR SYSTEM	SORING GMBH SONOCA 300
Applicant	SORING GMBH MEDIZINTECHNIK	AROBELLA MEDICAL, LLC	MISONIX, INC.	SORING GMBH MEDIZINTECHNIK
Classification Product Code	LFL	NRB, FQH, LFL	LFL	LFL BTA
Decision Date	11/13/2001	01/03/2007	06/06/2005	09/23/1999
Classification Advisory Committee	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery

Device Description:

Ultrasonic-Assisted Wound Treatment using the Sonoca 180 / 185 applies low-frequency power ultrasound in conjunction with an irrigation solution via a moving receptacle directly to the wound tissue. An ultrasonic generator transfers electric energy to a receptacle where a high-precision piezoelectric crystal system (PZT transducer) transforms this energy into mechanic vibrations: 25,000 vibrations / second (= 25 kHz).

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The receptacle is continuously moved over the wound surface. This allows gentle loosening of necrotic tissue and fibrin layers and flushes them away with the irrigation solution (0.9 % NaCl or Ringer solution). The liquid is used for transmitting the ultrasound as well as for wound irrigation. Cavitation is the underlying mode of action of ultrasound: the formation and disintegration of cavities (bubbles) in liquids due to pressure fluctuations, i.e. formation and subsequent implosion of these bubbles causes turbulences and currents on the wound surface, which help to loosen necrotic tissue and fibrin layers.

Indications for Use:

The SONOCA 180/185 Wound Care System is an instrument intended for selected ultrasound dissection and fragmentation of tissue, wound debridement (acute and chronic wounds, burns, diseased or necrotic tissue) and cleansing irrigation of the site for removal of debris, exudates, fragments, and other matter.

Performance Data:

The subject device complies with IEC 950 – Safety of Information Technology Equipment, CISPR 22, class A – Electromagnetic Compatibility, IEC-801-2, IEC-801-3 – Electromagnetic Compatibility, IEEE 1003.1 – General Electrical Safety for medical devices, IEC 601-1 –Electrical Safety for medical devices using RF-power, IEC 601-2-2 – Ultrasonic surgical devices, DIN EN 61847

Conclusion:

Similar to the predicate devices, the Sonoca 180/185 does not control any life sustaining functions or services.

The new device and the predicate devices are substantially equivalent in the areas of general function, and intended use. Any differences between the devices will not affect safety or efficacy.

Based on the information supplied in this 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2009

Soring GmbH
% Delta Quality Consulting
Mr. Carl Thomas
1600 Manchester Way
Corinth, Texas 76210

Re: K072904
Trade/Device Name: Sonoca 180/185 Wound Care System
Regulatory Class: Unclassified
Product Code: LFL
Dated: May 12, 2008
Received: May 19, 2008

Dear Mr. Thomas:

This letter corrects our substantially equivalent letter of May 21, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, M.D.

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K072904

Device Name: Soring GmbH, SONOCA 180/185 Wound Care System

Indications for Use:

The SONOCA 180/185 is an instrument intended for selected ultrasound dissection and fragmentation of tissue, wound debridement (acute and chronic wounds, burns, diseased or necrotic tissue) and cleansing irrigation of the site for removal of debris, exudates, fragments, and other matter.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072904